MAY 1 2 2014

510(k) Summary
(per 21 CFR 807.92)

1.Applicant

Future Device and Technology, Inc.
4322 Wilshire Blvd., Suite 303
Los Angeles, CA 90010
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Date Prepared: July 12, 2013

2. Device Name

Proprietary/Trade Name: Gallieon-1
Common/Usual Name: Infrared Lamp
Classification Name: Lamp, Infrared, therapeutic heating
Regulation Number: 890.5500
Product Code: ILY
Classification: II
Panel: Physical Medicine

3. Predicate Devices

The Gallieon-1 is equivalent to the following devices:

510(k) number	Device	Manufacturer
K031612	ALT Laser, Model VTR 75	Avicenna Laser Technology, Inc.
K050070	Klaser Therapy Probe	Eltech, S.R.L
K083560	ESPT-3X	Light Technical Innovation, Inc.

4. Intended Use of the device

The Gallieon-1 system is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for

- the temporary relief of minor muscle and joint pain and stiffness
- relief of minor pain and stiffness associated with arthritis
- relief of muscle spasm
- the temporary increase in local blood circulation
- promoting relaxation of muscle/ligament

The Gallieon -1 SYSTEM is for prescription use only.

5. Description of the Device

Gallieon-1 is a non-invasive, low energy infrared therapeutic medical laser that is intended to perform laser therapy in the health care centers, physical therapy laboratories, and family practices. It is composed of adjustable output powers, handpiece (emitter) for the delivery of light, on/off button to activate and deactivate the infrared emission. Also Gallieon-1 meets FDA requirement of the skin temperature test and the electromagnetic compatibility and electrical safety test.

6.Technical Characteristics and Substantial Equivalence

Gallieon-1 generates infrared therapy for treatment of selected medical conditions and shares the same or similar basic characteristics and the same intended use as the predicate device. Therefore, the proposed Gallieon-1 is substantially equivalent to Altlaser, Model VTR 75, cleared under K031612; to Klaser therapy probe, cleared under K050070; to ESPT (Expanded Spectrum Photo Therapy Device)-3X, cleared under K083560.

7. Safety and Effectiveness

There are no substantive differences between the product defined in this 510(k) submission and the predicate device. They are similar to the technologies that are currently used in other similar medical devices. In addition,The Gallieon-1 was tested extensively to ensure conformance to applicable standards and FDA regulations. The Gallieon-1 meets the applicable requirement of CFR 1040 part 820, under design/change control, and verified/validated to applicable standards/guidance documents.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 12, 2014

Future Device and Technology Incorporated
Mr. Soung Don Chung
Chief Executive Officer
4322 Wilshire Boulevard, Suite 303
Los Angeles, California 90010

Re: K132529
Trade/Device Name: Gallieon-1
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: April 18, 2014
Received: April 22, 2014

Dear Mr. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132529

Device Name
Gallieon-I

Indications for Use *(Describe)*
The device is indicated for emitting energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

David Krause -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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